

Amendments to the Claims:

Following is a complete listing of the claims pending in the application, as amended:

1. (Currently Amended) A nucleic acid expression cassette capable of expressing human Factor IX, wherein the cassette is predominantly expressed in the mammalian liver ~~of a post-natal subject~~, said cassette comprising:

(a) [[an]] a hepatic locus control element consisting of SEQ ID NO:4 or SEQ ID NO:9;

(b) [[an]] a heterologous hepatic promoter located 3' to the hepatic locus control element, said promoter consisting of a human  $\alpha$ -1 antitrypsin promoter (SEQ ID NO:5);

(c) a Factor IX coding sequence located 3' to the hepatic promoter, said coding sequence comprising SEQ ID NO:2;

(d) a polyadenylation signal located 3' to the intron sequence, said polyadenylation signal consisting of SEQ ID NO:6; and

(e) an intron located 3' to the hepatic promoter and 5' to the polyadenylation signal, wherein said intron consists of SEQ ID NO:1,

wherein elements (a), (b), (c), (d) and (e) are operably linked to express the polypeptide encoded by the coding sequence.

2. (Currently Amended) The expression cassette of claim 1, wherein said cassette directs expression of a therapeutic amount of Factor IX in liver cells for a period of at least 100 days, and further wherein said cassette is expressed in ~~a transgenic~~ an animal or as a component of a recombinant adeno-associated virus (AAV) vector.

3. (Currently Amended) The expression cassette of claim 1, wherein said cassette directs expression of a therapeutic amount of the polypeptide in liver cells for a period of at least 300 days, and further wherein said cassette is expressed in ~~a transgenic~~ an animal or as a component of a recombinant adeno-associated virus (AAV) vector.

4. (Currently Amended) The expression cassette of claim 1, wherein said cassette directs expression of a therapeutic amount of the polypeptide in liver cells for a period of at least 500 days, and further wherein said cassette is expressed in a transgenic an animal or as a component of a recombinant adeno-associated virus (AAV) vector.

5-14. Canceled

15. (Previously Presented) A nucleic acid expression cassette capable of expressing human Factor IX, wherein the cassette is predominantly expressed in the mammalian liver, said cassette comprising:

- (a) a hepatic locus control element consisting of SEQ ID NO:4 or SEQ ID NO:9;
- (b) a hepatic promoter located 3' to the hepatic locus control element, said promoter consisting of SEQ ID NO:5;
- (c) a Factor IX coding sequence located 3' to the hepatic promoter, said coding sequence comprising SEQ ID NO:2;
- (d) a polyadenylation signal located 3' to the intron sequence, said polyadenylation signal consisting of SEQ ID NO:6; and
- (e) an intron located 3' to the hepatic promoter and 5' to the polyadenylation signal, wherein said intron consists of SEQ ID NO:1, and
- (f) an untranslated region located 3' to the coding region and the intron, said untranslated region consisting of SEQ ID NO:7;

wherein elements (a), (b), (c), (d) and (e) are operably linked to express the polypeptide encoded by the coding sequence.

16-23. Canceled

24. (Previously Presented) A nucleic acid expression cassette capable of expressing human Factor IX, wherein the cassette is predominantly expressed in the mammalian liver, said cassette comprising:

(a) a hepatic locus control element comprising an enhancer sequence consisting of SEQ ID NO:8;

(b) a heterologous hepatic promoter located 3' to the hepatic locus control element, said promoter consisting of a human  $\alpha$ -1 antitrypsin promoter (SEQ ID NO:5);

(c) a Factor IX coding sequence located 3' to the hepatic promoter, said coding sequence comprising SEQ ID NO:2;

(d) a polyadenylation signal located 3' to the intron sequence, said polyadenylation signal consisting of SEQ ID NO:6; and

(e) an intron located 3' to the hepatic promoter and 5' to the polyadenylation signal, wherein said intron consists of SEQ ID NO:1;

wherein elements (a), (b), (c), (d) and (e) are operably linked to express the polypeptide encoded by the coding sequence.

25-35. Canceled

36. (Currently Amended) The expression cassette of claim 15, wherein said cassette directs expression of a therapeutic amount of Factor IX in liver cells for a period of at least 100 days, and further wherein said cassette is expressed in ~~a transgenic~~ an animal or as a component of a recombinant adeno-associated virus (AAV) vector.

37. (Currently Amended) The expression cassette of claim 15, wherein said cassette directs expression of a therapeutic amount of the polypeptide in liver cells for a period of at least 300 days, and further wherein said cassette is expressed in ~~a transgenic~~ an animal or as a component of a recombinant adeno-associated virus (AAV) vector.

38. (Currently Amended) The expression cassette of claim 15, wherein said cassette directs expression of a therapeutic amount of the polypeptide in liver cells for a period of at least 500 days, and further wherein said cassette is expressed in ~~a transgenic~~ an animal or as a component of a combinant recombinant adeno-associated virus (AAV) vector.

39. Canceled

40. (Currently Amended) The expression cassette of claim 24, wherein said cassette further includes an untranslated region located 3' to the coding region and the intron, said untranslated region consisting of SEQ ID NO:7, and wherein said cassette directs expression of a therapeutic amount of Factor IX in liver cells for a period of at least 100 days, and further wherein said cassette is expressed in a transgenic an animal or as a component of a recombinant adeno-associated virus (AAV) vector.

41. (Currently Amended) The expression cassette of claim [[24]] 40, wherein said cassette directs expression of a therapeutic amount of the polypeptide in liver cells for a period of at least 300 days, and further wherein said cassette is expressed in a transgenic animal or as a component of a recombinant adeno-associated virus (AAV) vector.

42. (Currently Amended) The expression cassette of claim [[24]] 40, wherein said cassette directs expression of a therapeutic amount of the polypeptide in liver cells for a period of at least 500 days, and further wherein said cassette is expressed in a transgenic animal or as a component of a recombinant adeno-associated virus (AAV) vector.

43. Canceled